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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER
HELMER, GEORGIA L

ART UNIT	PAPER NUMBER
1638	4

DATE MAILED: 01/14/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/856,976	KURAYA ET AL.	
	Examiner	Art Unit	
	Georgia L. Helmer	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 October 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Status of the Claims

1. The Office acknowledges receipt of Applicants Response; dated 23 October 2002, paper number 8.

2. Applicant has amended claims 1-6, and added new claims 8-14. Claims 1-14 are pending, and are examined in the instant action.

3. This action is made FINAL necessitated by Applicant's amendment.

4. All rejections not addressed below have been withdrawn.

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112 second

6. Claims 1-14 are rejected under 35 U.S.C. 112, second paragraph; claims 1-7 remain rejected for reasons of record and this rejection is extended to new claims 8-14. To the extent that this is a new rejection, it is necessitated by Applicant's amendment.

Claim 1 was previously rejected because

- "based" on the function of Agrobacterium" is unclear. Does this mean physically based on the use of Ti plasmids, so that Ti plasmid components are incorporated? It is unclear whether or not an Agrobacterium vector is required. Or does it mean a system analogous to Agrobacterium transformation vectors? This language is further unclear because Agrobacterium has many functions and no particular function is specified.

Applicant has amended the claim to recite "for Agrobacterium based plant transformation", and states (Response, p 7) that this phrase means "that the vir proteins of Agrobacterium recognize the border regions of the vector carrying the T-DNA so that the vector main be introduced into the plant".

The language for "Agrobacterium based plant transformation" remains indefinite for reasons of record. It is unclear what the components of the system are—are they solely DNA? Or solely Agrobacterium? Or are both required? And especially: Is Agrobacterium required for transformation? All subsequent recitations of this language is also rejected. Claims 1-14 are rejected.

In claims 2 and 14, it is unclear what function is associated with "recognized".

Claims 5 and 6 of the marked-up copy are not the same as the clean copy; the spelling mistake of Agrobacterium remains in the marked-up copy. The marked-up copy of the claims should be the same as the clean copy of the claims.

Claims 6, 8, 9, and 10 are incomplete methods claims, as the final step of the claim does not produce the desired product.

Claim Rejections - 35 USC § 112-new matter

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 1-14 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The amended claims and new claims are drawn to a vector which "prevents integration of a non-T-DNA segment into a plant chromosome." This limitation is not supported by the application as originally filed, and therefore is new matter. This is a new rejection, necessitated by Applicant's amendment, and is therefore made final.

Claim 4 has been amended to recite a "marker", in place of a "marker gene". A "marker" is broader than a "marker gene". This limitation is not supported by the application as originally filed, and therefore is new matter. This is a new rejection, necessitated by Applicant's amendment, and is therefore made final.

Claim Rejections - 35 USC § 112 first paragraph-Enablement

9. Claims 1- 14 are rejected under 35 U.S.C. 112, first paragraph; claims 1-7 remain rejected under 35 U.S.C. 112, first paragraph and this rejected is extended to new claims 8-14 because the specification,

- while being enabling for an Agrobacterium vector for plant transformation wherein the left border sequence has been modified to include one or two additional repeats of the T-DNA left border (LB) sequence,
- does not reasonably provide enablement for all modifications of the LB sequence, or for a vector which "prevents" integration of a non-T-DNA segment into a plant chromosome.

The enablement issues are "modified" DNA, and a vector which "prevents" integration. The rejection based on "modification", for reasons of record, is maintained from the previous Office Action. The rejection based on "prevention" of integration is a new rejection, necessitated by Applicant's amendment, and is therefore made final.

With respect to the issue is DNA "modified" to do something:

Applicant traverses, stating primarily the modifications may be deletions, substitutions or additions of one or more nucleotides in the existing LB recognized by the vir proteins; deletions, substitutions or additions of one or more nucleotides near the existing LB which allow more efficient recognition; the plurality of any sequences that are recognized by vir proteins, and any combination of any of these above. And that the specification includes examples of the modified LB region—these examples include one, two or three additional repeats of the T-DNA LB sequence. And that for these reasons the quantity of experimentation needed to make and use the present invention is not undue.

Applicant's traversal has been considered and is unpersuasive because

Applicant claims all modifications but teaches only one modification—that of repeated LB sequences. While Applicant enumerates various modifications, Applicant only gives guidance as to how to make and use repeats of the LB sequence. "Modification" encompasses a virtually ad infinitum number of possible combinations and permutations. One skilled in the art would be required to make an infinite number of modifications to the DNA, and without further guidance, would need to do numerous experiments, choosing from myriads of combinations of additions, substitutions and deletions to find a modified DNA capable of functioning as recited in claim 1, most of which modifications are unlikely to be operable. Applicant presents a working example, comprising either one or two, additional LB sequences. One skilled in the art can readily make all modifications, however one needs further guidance as to what modification would result in preventing of integration of non-T-DNA sequences into plant chromosomes, without undue experimentation.

With respect to a vector which "prevents" integration of a non-T-DNA segment into a plant chromosome;

- Applicant's original claims were drawn to a modification to "reduce the possibility of integration of any non-T-DNA segment into the plant

chromosomes". Applicant has amended claims to recite a vector which "prevents" integration of a non-T-DNA segment into a plant chromosome;

- Applicant does not teach a "prevention of " integration of a non-T-DNA segment into a plant chromosome. Prevention means that an effect does not happen, that to the extent necessary, something is done or something manipulated, in order to cause an effect not to occur at all. Prevention is a more stringent standard than reduction; prevention is a qualitative measure and reduction is a quantitative measure. Prevent means it never happens.
- Applicant teaches a reduction in integration frequency of non-T-DNA sequences. A reduction in integration frequency is not a prevention of integration. Applicant has provided no guidance as to what the vector must contain or what must be modified to prevent integration. Applicant does not teach one skilled in the art how to prevent integration. One skilled in the art can make modifications, but without further guidance, would not know what modifications would function to prevent integration of non-T-DNA, or how to systematically avoid inoperable embodiments, which is random trial and error experimentation and constitutes an undue burden.

Accordingly, the claimed invention is not enabled as commensurate in scope with the claims.

Claim Rejections - 35 USC § 102

10. Claims 1, 2, 4-10 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Becker et al (Plant Molecular Biology 20: 1195-1197, 1992). Claims 1, 2, and 4-7 remain rejected for reasons of record. This rejection is extended to new claims 8-10 and 14.

It would appear that Becker inherently teaches the modified LB, as discussed in the previous Office Action, part of which is repeated below.

Becker teaches:

- An Agrobacterium plant transformation vector (pg 1195, 1st paragraph). Since there is no evidence of integration of any non-T-DNA segment into plant chromosomes, the vector of Becker inherently possesses the left border sequence modification set forth in the claims. Additionally, since the Agrobacterium transformation vector system utilized by Becker results in successful expression of the selectable marker in transformed plants (p1196, 1st column), the border sequences would have been recognized by the vir proteins of Agrobacterium. Becker also teaches a T-DNA region between the border sequences, insertion of the selectable marker, and the replication origin (p 1196, Figure 1, and 2nd column).

Applicant traverses, stating primarily that Becker merely teaches new plant binary vectors with selectable markers located proximal to the left T-DNA border.

And that Becker does not disclose the modification Office Action the left border region per se.

Applicant's traversal has been considered and is unpersuasive because, even though Becker does not specifically recite a modified LB, the method of Becker results in a T-DNA transformation and there is no evidence for integration of any non-T-DNA segment in the plant chromosomes. Since the method of Becker is applied to the same plant population as in the instant case, and since the method of Becker results in T-DNA transformation with no evidence for integration of any non-T-DNA segment in the plant chromosomes, the claimed invention is not distinguishable from method of Becker.

REMARKS

11. No claim is allowed.

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Georgia L. Helmer whose telephone number is 703-308-7023. The examiner can normally be reached on 8:30 - 5:00. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on 703-306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Georgia L. Helmer PhD
Patent Examiner
Art Unit 1638
January 12, 2003

PHUONG T. BUI
PRIMARY EXAMINER 1/13/03